

AMENDED CLAIM 2-MARKED UP VERSION

2. (amended) The method according to claim 1, wherein the fat-containing food contains from about 10 kcal%fat.

REMARKS

Claims 28-36 have been canceled without prejudice or disclaimer. Claim 2 has been amended to more distinctly claim that which Applicants regard as their invention. It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

1. Restriction Requirement

The following Restriction Requirement was issued under 35 U.S.C. 121:

- I. Claims 1-27, drawn to a method for reducing the consumption of fat-containing food comprising a compound of the structural formula (I) and
- II. Claims 28-36, drawn to a method for reducing the consumption of fat-containing food comprising a potassium channel agonist

The Examiner has also required Applicants to elect a single specified individual active compound to be employed in the claimed method.

During a telephone conversation with the Examiner on January 4, 2002, Applicants' representative provisionally elected with traverse to prosecute the invention of Group I, claims 1-27 and the species recited in claim 27. Applicants hereby affirm the election with traverse of Group I and the species recited in claim 27. As a result, Applicants have canceled claims 28-36, but reserve the right to file subsequent continuation and/or divisional applications reciting the subject matter of said canceled claims 28-36. However, Applicants do note that as stated in the Office Action, upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

2. Rejections Under 35 U.S.C. §112, Second Paragraph

Claim 2 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their

invention. Specifically, it is asserted that the expression "from 10 kcal%fat" in claim 2 renders claim 2 indefinite. In response, claim 2 has been amended to recite "at least about 10 kcal%fat". This claim amendment, in Applicants' view, overcomes the rejection of claim 2 under 35 U.S.C. 112, second paragraph. Therefore, Applicants respectfully request that the rejections be withdrawn.

3. The Rejection Under 35 U.S.C. 103

Claims 1-12, 19-24 and 26-27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (US5889002, WO9726265 and WO9903861) (hereinafter "Nielsen references") in view of Applicant's admission regarding the prior art. It is asserted that the Nielsen references disclose that the active compounds represented by the general formula I covering the instant elected species are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly and that these references teach that potassium channel openers are also known to be useful in the treatment of obesity and decreasing weight gain. It is conceded that the Nielsen references do not expressly disclose a method for reducing the consumption of fat-containing food employing the active compounds. However, the Examiner asserts that Applicant's admission regarding the prior art teaches that the amount of fat-containing food to be consumed or fat intake is tightly associated with the risk of obesity, hypertension, diabetes, coronary heart disease and notes that Applicant admitted that potassium channel openers are also known to be useful in the treatment of obesity and decreasing weight gain. Therefore, it is concluded that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the active compounds of Nielsen et al., represented by the general formula I therein, in a method for reducing the consumption of fat-containing food and to employ food containing from 10-45kcal% fat. The Examiner further states:

since the active compounds of Nielsen are known to be potassium channel openers are therefore known to be useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart disease diabetes and obesity, and decreasing weight gain. Moreover, since the amount of fat-containing food to be consumed or fat intake is well known to be tightly associated with risk of obesity,

hypertension, diabetes, and coronary heart disease according to the prior art, one of ordinary skill in the art would have reasonably expected that the active compounds of Nielsen would have beneficially therapeutic effect on reducing the consumption of fat-containing food.

Applicants respectfully traverse the rejection. Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under §103 requires *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

As will be discussed below, given the varying teachings of the prior art, it is questionable as to whether the prior art would have suggested that the compounds of general formula I could be used in the treatment of obesity. Further, contra to the Examiner's assertion, one of ordinary skill in the art would not have reasonably expected that the active compounds of Nielsen would have a beneficial therapeutic effect on reducing the consumption of fat-containing food. First, Applicants note that as conceded in the Office Action, there is no teaching in any of the Nielsen references that the compounds represented by the general formula I could be used for reducing the consumption of fat-containing food. The potassium channel opener disclosed by Nielsen to be useful in the treatment of obesity and decreasing weight gain, diazoxide, is very different from the compounds of the general formula I. Further and most importantly, Applicants in the instant application also disclose that intracerebroventricular administration of the potassium channel openers minoxidil and pinacidil increases intake of food by mice. Details are provided Ghelardini et al., 1997, Eur. J. Pharmacol. 329:1-8 (cited in the Information Disclosure Statement). Additionally, Applicants disclose that the potassium channel blocker, glybenclamide, reduces food intake. A detailed hypothesis is provided in Roane, 1993, Pharm. Biochem. Behavior 46:205-207 (cited in the Information Disclosure Statement). Therefore, given these two disclosures, one of ordinary skill in

the art would not have a reasonable expectation of success that a potassium channel opener would necessarily reduce food intake.

In view of the above arguments, Applicants assert that the rejections under 35 U.S.C. 103 have been overcome. Therefore, Applicants respectfully request that the rejections be withdrawn.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Dated:

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